DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 30 1987

#10

RECEIVED IN
DIRECTOR'S OFFICE
FEB 4 1987
GROUP 120

Re: Tegison
Docket No. 86E-0491

The Honorable Donald J. Quigg
Assistant Secretary of Commerce
and Commissioner of Patents and Trademarks,
Washington, DC 20231

Dear Commissioner Quigg:

This is in regard to the application for patent extension for U.S. Patent No. 4,215,215, filed by Hoffmann-LaRoche, Inc., under 35 U.S.C. 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Tegison, the human drug product claimed by the patent.

The total length of the review period for Tegison is 3,640 days. Of this time, 2,989 days occurred during the testing phase and 651 days occurred during the approval phase. The periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: October 14, 1976.

   FDA has verified the applicant's claim that the notice of claimed investigational exemption for the drug product became effective on October 14, 1976.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: December 19, 1984.

   The applicant claims that a new drug application for the product (NDA 19-369) was initially submitted on December 20, 1984. However, FDA records indicate that the application was initially submitted on December 19, 1984.

3. The date the application was approved: September 30, 1986.

FDA has verified the applicant's claim that NDA 19-369 was approved on September 30, 1986.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent nor does it exclude one-half of the testing phase as required by 35 U.S.C. 156 (c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Jon S. Saxe, Esq.
340 Kingsland Street
Nutley, NJ 07110